K111612

510(k) Summary

SEP 14 2011

Prepared: Sept 12, 2011

Company Name:	CANON INC.
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Proposed Device:

Reason For 510(k):	New Model
Trade Name:	Canon Digital Retinal Camera CR-2 Plus
Regulation Number:	21 CFR 886.1120
Regulation Name:	Ophthalmic camera
Regulatory Class:	II
Product Code:	HKI
FDA 510(k) #:	K111612

Predicate Device:

Trade Name:	Canon Digital Retinal Camera CR-2
Regulation Number:	21 CFR 886.1120
Regulation Name:	Ophthalmic camera
Regulatory Class:	II
Product Code:	HKI
FDA 510(k) #:	K102013

Trade Name:	Canon Digital Retinal Camera CX-1
Regulation Number:	21 CFR 886.1120
Regulation Name:	Ophthalmic camera
Regulatory Class:	II
Product Code:	HKI
FDA 510(k) #:	K092565

Description of Device:

The Digital Retinal Camera CR-2 Plus is used for taking digital images of a human retina without a mydriatic. Canon EOS Digital Camera is mounted to the CR-2 Plus. Images can be viewed immediately, making procedures more efficient with many different applications, such as telemedicine and electronic filing.

Indications for Use:

The CR-2 Plus is intended to be used for taking digital images of the retina of the human eye without a mydriatic. The CR-2 Plus has the following photography modes: color, red free & cobalt digital filter, and fundus autofluorecence (FAF).

Summary of Modifications to the Predicate Devices

The CR-2 Plus is a modification version to CR-2. The imaging principle and intended use are similar to those of CR-2 and CX-1. The major modifications are listed in the table below:

Table of Modifications

Item	Modifications to CR-2	Similar to CX-1
Operation mode	Add fundus autofluorecence photography mode	Yes
Light Source	Use Xenon Lamp (Max 255Ws) for photography (White LED is used in CR-2)	Yes
Software	1. Add CR-2 Plus as a target device 2. Activated FAF exposure mode which had been just implemented with "Rics for CX-1" 3. Add a GUI control of working dot brightness adjustment 4. Add ISO 200, 400, 800 into ISO speed choices 5. Add a speed priority (JPEG capture) mode	Software has been updated from CR-2 and CX-1

Substantial Equivalence

The CR-2 plus has the same intended use and similar principles of operation and technological characteristics as the predicate device. Performance testing on optical radiation safety and fundus autofluorecence photographing demonstrate the minor technological differences between the CR-2 Plus and the predicate devices do not raise any new questions of safety and effectiveness. Therefore, we believe the Digital Retinal Camera CR-2 Plus is substantially equivalent to Canon's legally marketed Digital Retinal Camera CR-2 and CX-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Canon, Inc.
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Tokyo 113-0021 JAPAN

SEP 14 2011

Re: K111612
Trade Name: Canon Digital Retinal Camera CR-2 Plus
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic camera
Regulatory Class: II
Product Code: HKI
Dated: August 12, 2011
Received: August 15, 2011

Dear Mr. Kubo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known) : K111612

Device Name: CR-2 Plus

Indications for Use:

The CR-2 Plus is intended to be used for taking digital images of the retina of the human eye without a mydriatic. The CR-2 Plus has the following photography modes: color, red free & cobalt digital filter, and fundus autofluorecence (FAF).

Prescription Use X OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111612